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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte URI SAGMAN, MICHAEL ROSENBLUM, and
LON WILSON

Appeal 2009-007942
Application 10/623,110
Technology Center 1600

Decided: December 12, 2009

Before ERIC GRIMES, RICHARD M. LEBOVITZ, and STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a composition comprising an antigen-binding moiety covalently linked to a fullerene or nanotube, and to a method of treating a disease. The Patent Examiner rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 1, 3, 4, 6-10 and 12-19, which are all the pending claims, are on appeal. Claim 1 is representative and reads as follows:

1. A composition, comprising:

(i) a C_n-Ab, wherein C_n is a fullerene or nanotube comprising n carbon atoms, and Ab is a moiety comprising an antigen-binding site and is covalently linked to the C_n, wherein the antigen-binding site recognizes an antigen associated with a medical condition; and
(ii) a pharmaceutically-acceptable carrier.

The Examiner rejected claims 1, 3, 4, 6-10 and 12-19 under 35 U.S.C. § 103(a) as unpatentable over Erlanger,[1] Haberzettl,[2] and Williams.[3]

OBVIOUSNESS

The Issue

The Examiner's position is that Erlanger disclosed the possibility of covalent linkage between fullerenes and a specific monoclonal antibody and how to test for the linkage. (Fin. Rej. 3.) The Examiner found that Haberzettl taught fullerenes for drug delivery, and "successful drug delivery architectures will be enhanced by allowing them to target a particular tissue or organ." (*Id.*) The Examiner concluded it would have been obvious "to produce a fullerene tube attached to an antibody that recognizes an antigen

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[1] U.S. Patent No. 6,593,137 B1, issued to Bernard F. Erlanger et al., Jul. 15, 2003.
[2] C A Haberzettl, *Nanomedicine: destination or journey?*, 13 NANOTECHNOLOGY R9-R13 (2002).
[3] JA Williams et al., *Targeting and therapy of human glioma xenografts in vivo using radiolabeled antibodies*, 19 INT. J. RADIAT. ONCOL. BIOL. PHYS. 633-42 (1990).

and add a drug such as doxorubicin to enhance treatment of a disease as disclosed by Haberzettl." (*Id.* at 3-4.) To Appellants' argument that Haberzettl's disclosure lacked a grounding in chemistry for making the claimed compositions, the Examiner responded that "[t]he claims do not require a method of making or loading" (Ans. 6), and gave no explanation that the prior art disclosed or suggested a way to make the claimed compositions. The Examiner found Haberzettl's disclosure at R10-R11 of nanobot targeting mechanisms and payloads "sufficient to reject the instant claims." (*Id.*) The Examiner found Haberzettl's suggestion of enhancing disease treatment and reducing drug side effects sufficient motivation for combining the Erlanger and Haberzettl teachings. (*Id.* at 7.)

Appellants contend that "Haberzettl is directed to a hypothetical device that neither he nor any other worker has constructed or even shown how to construct." (App. Br. 4.) Appellants further argue that Haberzettl's "speculative and hypothetical" teachings give no motivation to combine them with Erlanger or Williams, and even if they did, there would have been no obvious modifications that would have had a reasonable expectation of success. (*Id.* at 5.)

The issue in this appeal is whether Appellants have shown that Haberzettl's teachings were insufficient to support finding a reasonable expectation of success in combining them with Erlanger or Williams.

Findings of Fact

1. Erlanger raised "the possibility of covalent linkage between fullerenes and a [fullerene-] specific monoclonal antibody." (Erlanger, col. 20, ll. 4-5.)

2. Haberzettl taught that for targeting drug delivery fullerenes, "[t]he most likely mechanisms to be employed are based on antigen/antibody interactions." (Haberzettl, R10.)

Principles of Law

> (I)f the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious.

In re Hoeksema, 399 F.2d 269, 274 (CCPA 1968) (footnote omitted).

"Obviousness does not require absolute predictability of success . . . [A]ll that is required is a reasonable expectation of success." *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988). "[T]he expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chemical Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).

Analysis

Erlanger disclosed the possibility that a fullerene and its cognate antibody might become covalently linked after incubation. (FF1.) The Examiner found that because "Erlanger used a fullerene specific antibody, however, [Erlanger] does not disclose an antibody which recognizes an antigen." Thus, it was necessary to examine other prior art to learn if a covalently linked composition of fullerene and antibody that recognized an antigen associated with a medical condition (as Appellants claim) was

suggested in the prior art. The Examiner found that Haberzettl provided the suggestion. (FF2.)

Appellants argued that Haberzettl and Erlanger could not have made the claimed composition obvious because Haberzettl and Erlanger did not disclose the chemistry needed to make the suggested covalently linked composition. The Examiner was unpersuaded because "[t]he claims do not require a method of making. . . ." (Ans. 6.) That was a mistake: "the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious." *Hoeksema*, 399 F.2d at 274. The Examiner did not explain why a fullerene would have reasonably been expected to covalently link to an antibody associated with a medical condition. Erlanger's statement of the "possibility of covalent linkage" referred to fullerene's cognate antibody, not the antibody referenced in Appellants' claim. In the absence of evidence that there was a known or obvious process for covalently linking a fullerene and a moiety comprising an "antigen-binding site [that] recognizes an antigen associated with a medical condition," we conclude that the rejection did not state a prima facie case of obviousness.

CONCLUSIONS OF LAW

Appellants have shown that the combined Erlanger and Haberzettl teachings were insufficient to support finding a reasonable expectation for making the claimed composition.

SUMMARY

We reverse the rejection of claims 1, 3, 4, 6-10 and 12-19 under 35 U.S.C. § 103(a) as unpatentable over Erlanger, Haberzettl, and Williams.

REVERSED

dm

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